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A critical re-assessment of the inclination of lower incisors

INAUGURAL-DISSERTATION

zur Erlangung der Doktorwürde der Zahnmedizin
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Dedication:

To my dear parents with thanks

Table of contents

1. Abstract

Aim: The aim of this study was to revisit the inclination of lower incisors on cephalograms. Reference values for the angulation of lower incisors and for symphyseal dimensions were obtained from a population far larger than in any in previous studies. An assessment was then performed to evaluate any possible association between the angulation of lower incisors and symphyseal morphology or skeletal pattern.

Material and Methods: The sample consisted of lateral cephalograms of untreated subjects (605 females and 677 males) aged eight to sixteen obtained from the Zurich Craniofacial Growth Study performed in the years of 1981-84. The cephalograms were traced and landmarked by hand and then digitized. Descriptive statistics for the measurements were computed. In order to disclose deterministic differences between the sexes, a one sample Student's t-test was applied. The assumption of normality of the variables was investigated by the Kolmogorov-Smirnov test. The Pearson correlation coefficient was performed to evaluate correlations between the variables.

Results: No deterministic differences between the sexes were found and all variables followed normal distribution, but with a wide interindividual span width. For lower incisor angulation (α), height (H1 and H2) and width (W), an age-dependent slight increase could be observed for both sexes. Symphyseal depth (D) decreased over age. Of all absolute symphyseal measurements, only symphyseal depth (D) correlated for most ages highly significantly with α. Similarly, no correlation could be established with α and symphyseal height to width ratios (H1/W and H2/W). Depth-to-width-ratio (D/W), however, correlated significantly with α for most ages. α seemed to be related to the skeletal pattern: significant and highly significant negative correlations could

be observed between variables representing the skeletal pattern such as the divergence of the jaws (DIV) or gonion angle (GO) and α, revealing that retroclined lower incisors were associated to divergent jaws and a wide gonion angle. This correlation seemed to be stronger in males than females and more prominent in late childhood.

Conclusion: The inclination of lower incisors (α) demonstrates strong interindividual variability. α is related to age, but is not associated to any symphyseal parameter except symphyseal depth (D and the ratio D/W). It seems therefore, that α is linked to the symphyseal space available posteriorly. α is clearly associated to the skeletal pattern. Based on all these findings, the use of a single reference value for lower incisor inclination is not to be recommended. Rather, the established factors affecting α are to be respected when establishing a treatment planning.

2. Introduction

The assessment of radiological characteristics of the mandible has become an essential part in orthodontic diagnosis and treatment planning. Two reasons are most frequently cited for evaluating mandibular morphology: First, the mandible is predominantly responsible for facial appearance and its growth pattern has an indisputable impact on facial development. Second, the anatomical shape of a mandible and specifically its symphyseal characteristics are thought to reflect past growth behavior and future tendencies (Ricketts, 1960).

Many efforts have been made to predict the growth of the mandible from a lateral cephalograph using several radiological parameters, with varying success. Notably, some studies attempted to determine whether the morphology of the symphysis could be used as predictor for future mandibular growth (Ricketts, 1960; Bjork, 1969; Sassouni, 1969; Skieller *et al.*, 1984; Lee *et al.*, 1987; Aki *et al.*, 1994; Leslie *et al.*, 1998).

Ricketts assumed that a thick symphysis is associated with an anterior growth direction (Ricketts, 1960). Björk suggested that the (1) inclination of the condylar head, (2) curvature of the mandibular canal, (3) shape of the lower border of the mandible, (4), anterior lower face height (5) interincisal angle, (6) interpremolar or intermolar angles and (7) symphysis morphology may provide information to predict the rotation pattern (Bjork, 1969). Concerning the latter, he observed that with a backward rotation of the mandible, the anterior part of the symphysis is flattened or almost straight. In an anterior rotation, the frontal border gained prominence owing to the rotation of the symphysis.

Skieller and coworkers established a prediction method for mandibular growth rotation (Skieller *et al.*, 1984). They reported that 86% of the variability of mandibular growth could be explained by using a combination of the following four cephalometric variables: (1) mandibular inclination, (2) intermolar angle, (3) shape of the lower border of the mandibula and (4) inclination of the symphysis with the rotation pattern.

In yet another study, symphysis morphology, particularly the ratio of height to width, was found to be indicative of the direction of mandibular growth. Subjects with shorter and wider symphysis showed greater amounts of anterior mandibular growth than subjects with longer and narrower symphysis (Aki *et al.*, 1994; Mangla *et al.*, 2011).

Finally, morphological changes have also been linked to physiological adaptation. More specifically, an increase in the function of the masticatory muscles has been associated with an anterior growth rotation pattern of the mandible (Kiliaridis, 1995). As stated above, several investigations related anterior growth rotation with a thick symphysis (Ricketts, 1960; Bjork, 1969; Aki *et al.*, 1994; Mangla *et al.*, 2011). It is noteworthy that a recent study using finite element analysis to examine symphyseal loads during masticatory function showed that changes in symphyseal form have profound effects on the strain (Groning *et al.*, 2011). The finding that the presence of a prominent chin may help resist higher symphyseal masticatory loads indeed corroborates the assumption that individuals with pronounced chin, i.e. individuals with an anterior growth rotation pattern, experience heavier masticatory forces.

Björk's and Skiller's findings are considered to be of high scientific relevance owing to their accurate methodology. But their clinical significance is, however, reduced by being confined to small cohorts of children with extreme growth patterns (Lux *et al.*, 1999).

Adopting the same four morphological indicators that Björk and Skieller had found to explain 86% of the cases, Lee and coworkers were not able to substantiate the associations published in the original publications (Lee *et al.*, 1987). Rather, using the longitudinal records of modest growers with fewer extreme cases, the four variables only accounted for 9% of the cases. A serious limitation in Lee's work, however, is the fact that some individuals received orthodontic treatment during the study.

Leslie and coworkers likewise challenged the predictive value of the findings of Björk and Skieller, stating that Skieller’s method was inadequate to permit clinically useful predictions (Leslie *et al.*, 1998).

In summary, the predictive value of radiological indicators on a larger population sample seems modest at best. Most of the morphologic criteria described by Björk (Bjork, 1969), Ricketts (Ricketts, 1960) or Skieller (Skieller *et al.*, 1984) do not contain information solid enough for a growth pattern prediction. Some evidence merely exist that the antegonial notch depth (Singer *et al.*, 1987; Lambrechts *et al.*, 1996) and specifically the morphology of the symphysis (Bjork and Skieller, 1983; Aki *et al.*, 1994; Mangla *et al.*, 2011; Papamanou *et al.*, 2012) may yield some information about the growth of the mandible. The relevance of the antegonial notch depth, however, has also been disputed by some investigators (Baumrind *et al.*, 1984; Kolodziej *et al.*, 2002).

2.1 Aim

Based on the assumption that symphyseal morphology may be the only reliable part of the mandible that contains information about the growth pattern of the mandible, it is of interest to discern whether the angulation of the lower incisors could be linked to a certain symphyseal morphology or skeletal pattern.

To the best of our knowledge, no investigation has been performed until now with the angulation of lower incisors as the endpoint. This approach, although uncommon, is reasonable, as the inclination of lower incisor is the only variable that can be easily modified during treatment. The aim of this present study was therefore to revisit the inclination of lower incisors on a population far larger than in any previous study, to obtain reference values for symphyseal dimensions and to reassess whether any symphyseal parameter or skeletal pattern could be used to disclose a change in angulation of lower incisors.

3. Materials and methods

3.1 Materials

The material consisted of lateral cephalograms obtained from the Zurich Craniofacial Growth Study performed in the years 1981-84. In the original study, 884 healthy, untreated schoolchildren of caucasian origin from local public schools were examined. The examination always took place very close to the individual's birthday, and 488 subjects had a second examination exactly a year later.

In this present study, lateral cephalograms of all subjects of the ages 8 - 16 years (1272 cephalograms, females: 605, males: 667) were used. Legal approval for releasing the data was obtained by the Federal Commission of Experts for Professional Secrecy in Medical Research (see 7.2).

3.2. Methods

The lateral cephalograms were taken with the head locked in position by ear rods and nasal support. The Frankfuter horizontal plane was set parallel to the floor and teeth were in centric occlusion. The x-rays were taken with a focus-coronal plane distance of 200cm and an enlargement of 7.5%.

Three investigators traced and landmarked the lateral cephalograms by hand as defined in Table 1 and shown in Figure 1. The digitizing was performed using tablet digitizer Numonics AccuGrid (Numonics, Landsdale, Pennsylvania, USA) with a resolution of 1 mili-Inch. A custom-made software was used for the calculation of the cephalometric values.

38 cephalograms were traced a second time more than 6 months apart, 19 by the same investigator and 19 by a different investigator, in order to determine intra- and interobserver reproducibility.

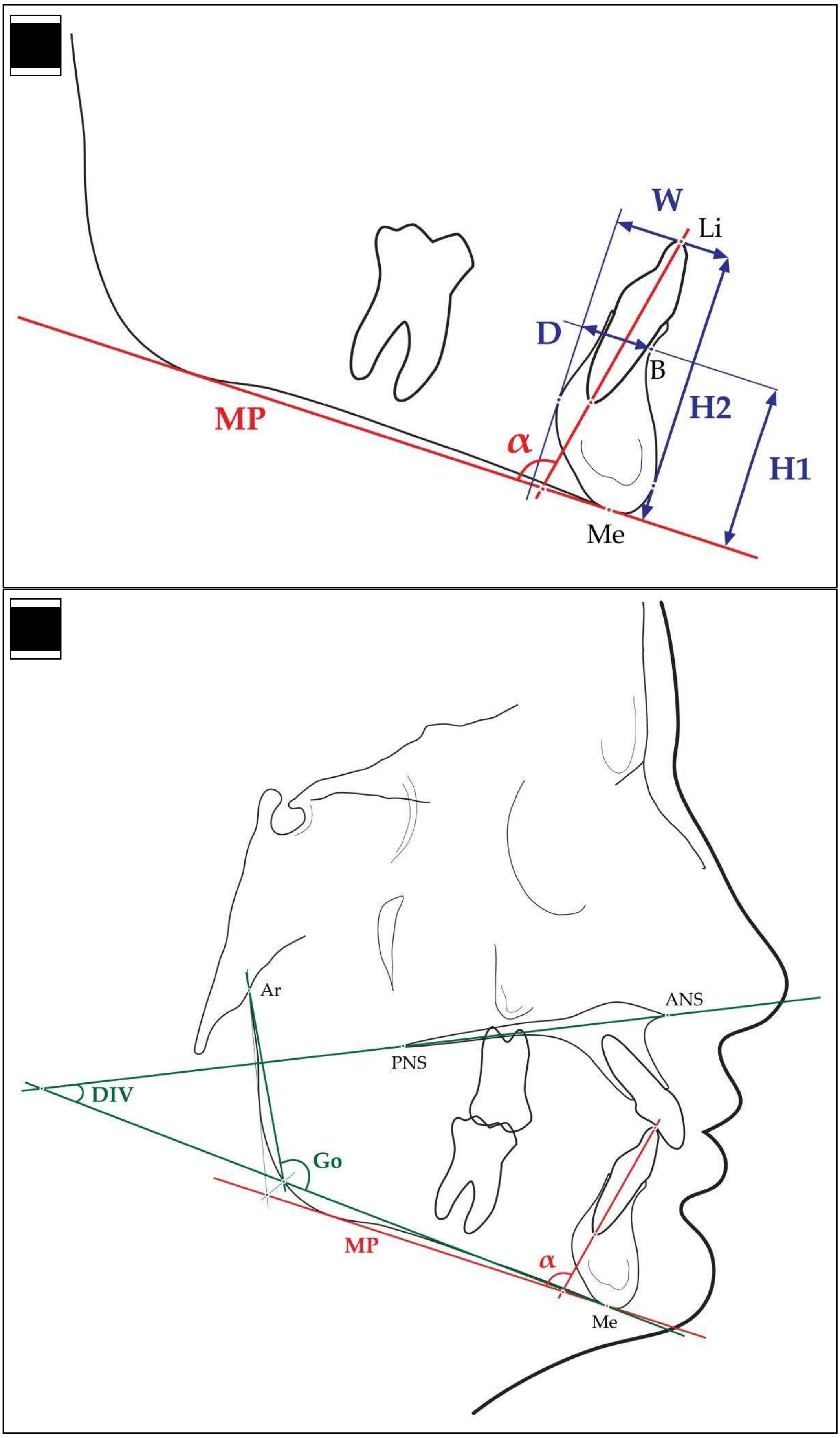

Fig. 1 (a & b)

Table 1: Definition of the landmarks

Parameters used in the statistical evaluation are in bold letters

	Definition
MP	Mandibular plane: Tangent to the lower mandibular border
α (°)	Angulation of lower incisor to mandibular plane
Symphyseal height	
B	Most posterior point of the bony curvature between the crest of the alveolar process and the chin
Li	Lower incisor: Tip of the anteriormost lower incisor
H1 (mm)	Perpendicular distance from point B to mandibular plane
H2 (mm)	Perpendicular distance from Li to mandibular plane
Symphyseal width	
W (mm)	Distance between the anterior and posterior tangents to the symphysis perpendicular to the mandibular plane
Symphyseal depth	
D (mm)	Distance between the posterior tangent to the symphysis perpendicular to the mandibular plane and a parallel line through B
Skeletal	
ANS	Anterior nasal spine: Most anterior point of the nasal floor
PNS	Posterior nasal spine: Most posterior point of the nasal floor
Me	Menton: Lowermost point of the contour of the mandibular symphysis
Go	Gonion: Midpoint of the angle of the mandible determined by bisecting the angle formed by the mandibular plane and the tangent to the posterior border through Articulare
Ar	Articulare: Point of intersection between the posterior mandibular ramus and temporal bone
DIV (°)	Divergence between the jaws defined as the angulation between the maxilla (anterior and posterior nasal spine as reference line) and the mandible (Menton to Gonion as reference line)
GO (°)	Gonion angle: angle formed between the lines Menton to Gonion and Gonion to Articulare

3.3 Statistical analysis

A standard statistical software package (IBM SPSS version 20, Armonk, New York, U.S.A.) was used for statistical analysis. To determine intra- and interobserver reliability, the intraclass correlation coefficient (ICC) for absolute agreement based on a one-way random effects analysis of variance (ANOVA) was calculated. Descriptive statistics for the measurements were computed. In order to disclose deterministic differences between the sexes, a one sample Student's t-test was applied. The assumption of normality of the variables was investigated by the Kolmogorov-Smirnov test. The Pearson correlation coefficient was performed to evaluate correlations between the variables. P-values smaller than 0.05 were considered as statistically significant.

4. Results

4.1 Inter- and intraobserver reliability

The intraclass correlation coefficient ICC, given in Table 2, revealed a very good repeatability for all cephalometric measurements. The mean value for all measurements was 0.948 (1 SD: ±0.142) for intraobserver repeatability and 0.933 (1 SD: ±0.141) for interobserver repeatability, respectively.

4.2 Descriptive Analysis

The distribution of the sample according to age and gender is listed in Table 3. Based on the fact that the records were taken always as close to the subject's birthday as possible, the mean, maximum and minimum of the ages for each group were consistently very close to the defined group age.

The Kolmogorov-Smirnov test revealed a normal distribution for all investigated variables, i.e. the inclination of lower incisors (α), both symphyseal heights (H1 and H2), the symphyseal width (W) and depth (D), as well as the skeletal parameters, i.e. the divergence of the jaws (DIV) and gonion angle (GO). Therefore, parametric tests were used for further statistical analysis.

Table 4 offers an overview of the mean values and the 95% confidence intervals of the symphyseal variables α, H1, H2, W and D. Figures 2-6 render those measurements in Box and whisker plots. For α, H1 and W an age-depended slight increase could be observed for both sexes. Similarly, an age-depended increase could be detected for H2, more pronounced in males. The symphyseal depth D decreased during the observed period.
No deterministic differences between the sexes were found for α.

4.3 Correlation Analysis

The correlation analysis revealed highly significant age dependency for all absolute symphyseal measurements in males, and significant to highly significant age dependency in females. The results of this correlation analysis are given in Table 5.

In a further step, correlations between α and symphyseal height (H1 and H2, respectively) as well as symphyseal width (W) and depth (D) were explored.
Table 6 demonstrates that no correlation could be found for H1 at any age, and not for H2 and W at almost any age (three exceptions) for both genders. In stark contrast, the symphyseal depth, however, correlated for most of the ages highly significantly with α. The ages where no highly significant correlation could be found were for females age 8 (just significant), age 12 and 16 (both not significant), and for males age 8 (not significant) and age 9 (just significant).

Additionally, the correlations between α and symphyseal ratios were studied in order to avoid biases based on absolute measurements. Height to width (both H1/W and H2/W) were analysed as well as depth to width (D/W). Table 7 reveals that no correlations could be established for H1/W and H2/W for almost all ages, males and females alike (two exceptions). Again, in plain contrast, α showed highly significant correlations in both genders for nearly all ages with the depth-to-width ratio. The ages where no highly significant correlation could be found were for females ages 8 and 11 (just significant) and 12 (not significant), and for males ages 8 (not significant) and 9 (just significant).

Moreover, the correlations between α and the skeletal pattern were examined. Two reference values, i.e. the divergence of the jaws (DIV) and gonion angle (GO), were used to portray the skeletal pattern. The results are subsumed in Table 8. Significant and highly significant correlations could be observed, but without consistency or pattern in any sex. It seems, however, that significant correlations appear more recurrently in males and in older age groups.

Fig. 2: Box and whisker plot for α

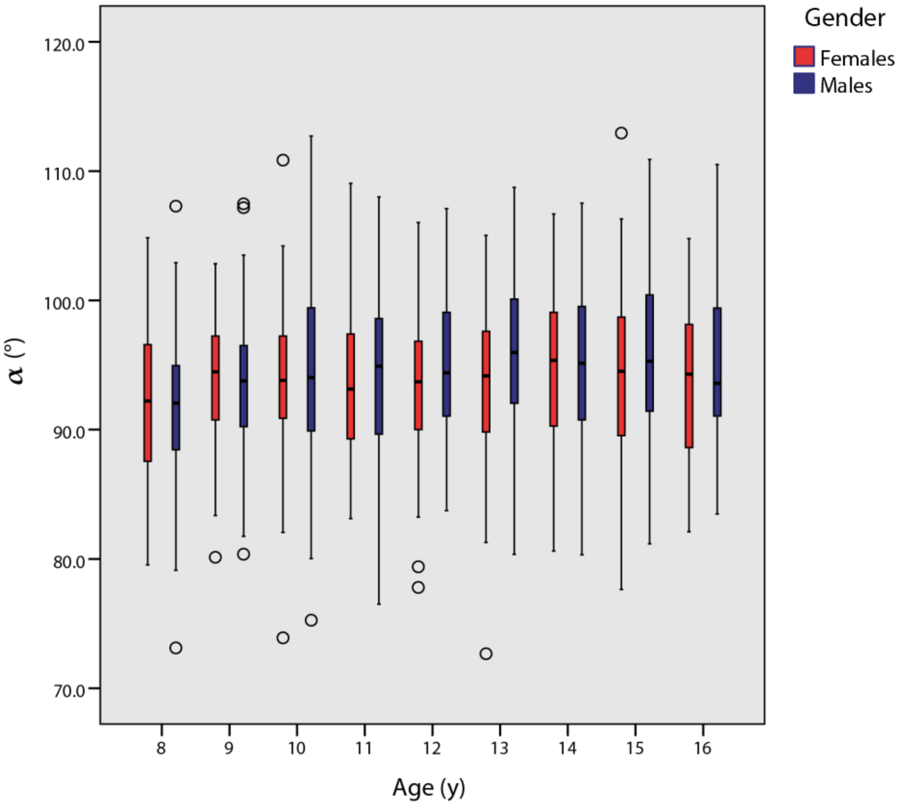

Fig. 3: Box and whisker plot for symphyseal height H1

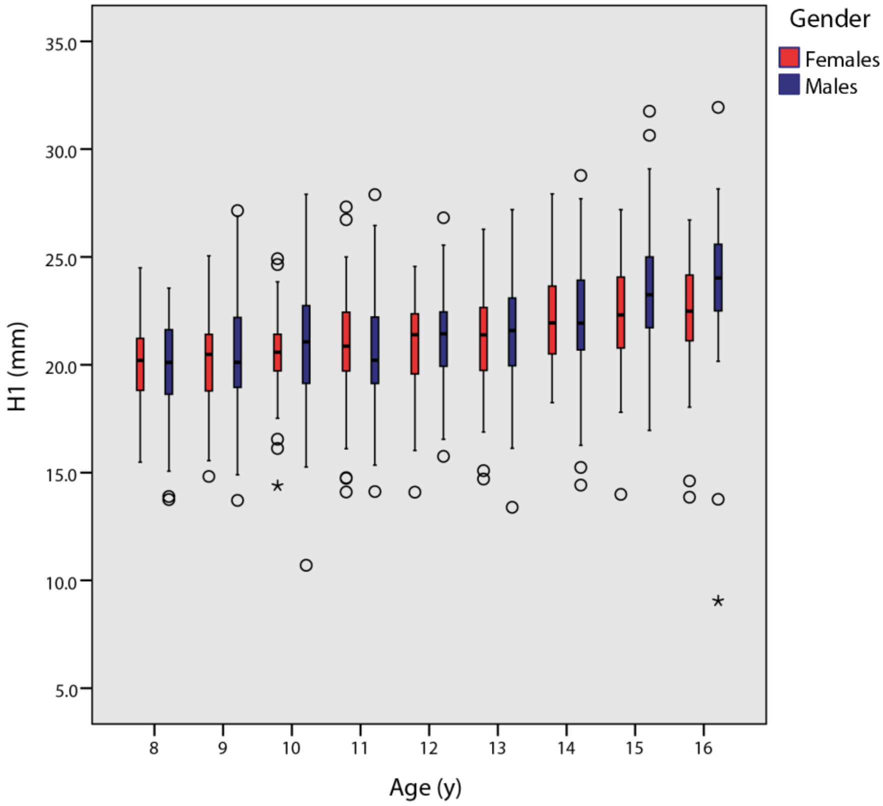

Fig. 4: Box and whisker plot for symphyseal height H2

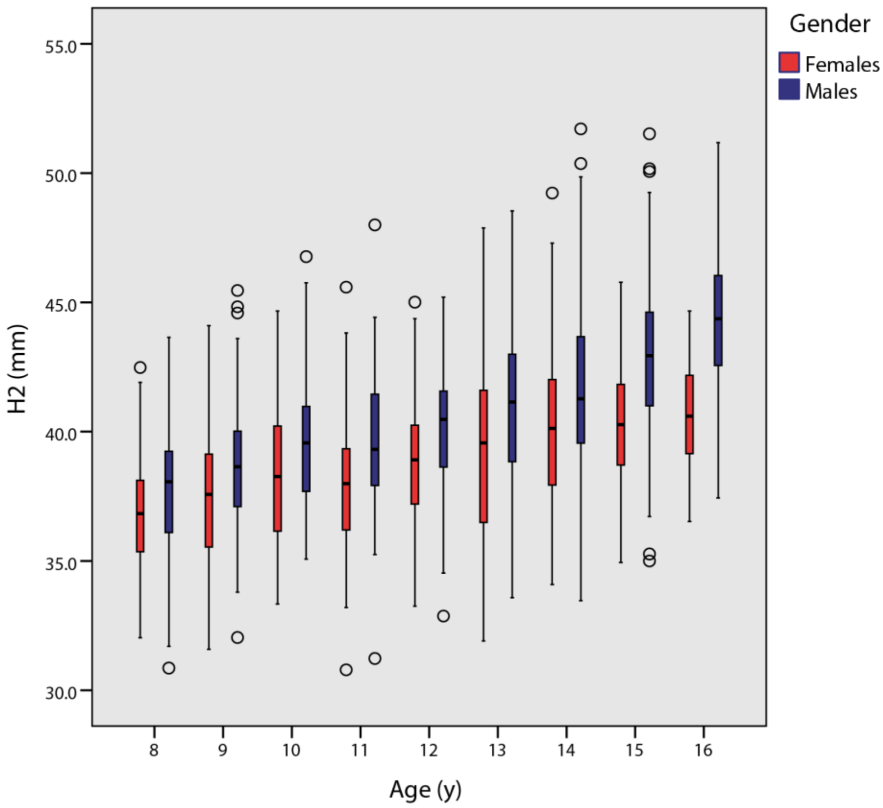

Fig. 5: Box and whisker plot of symphyseal width (W)

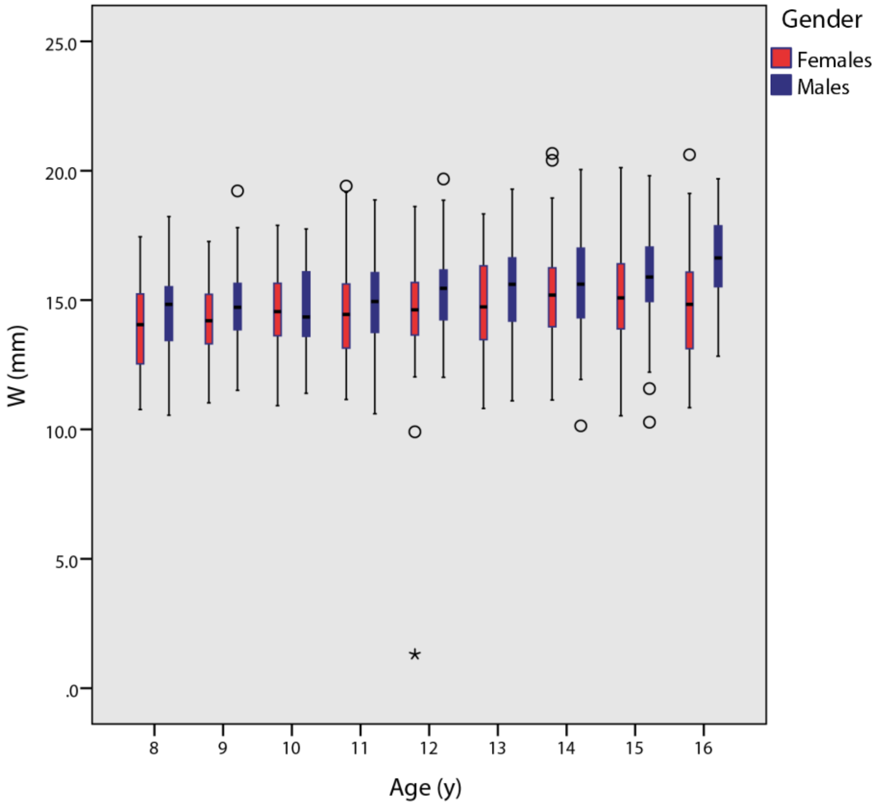

Fig. 6: Box and whisker plot for symphyseal depth (D)

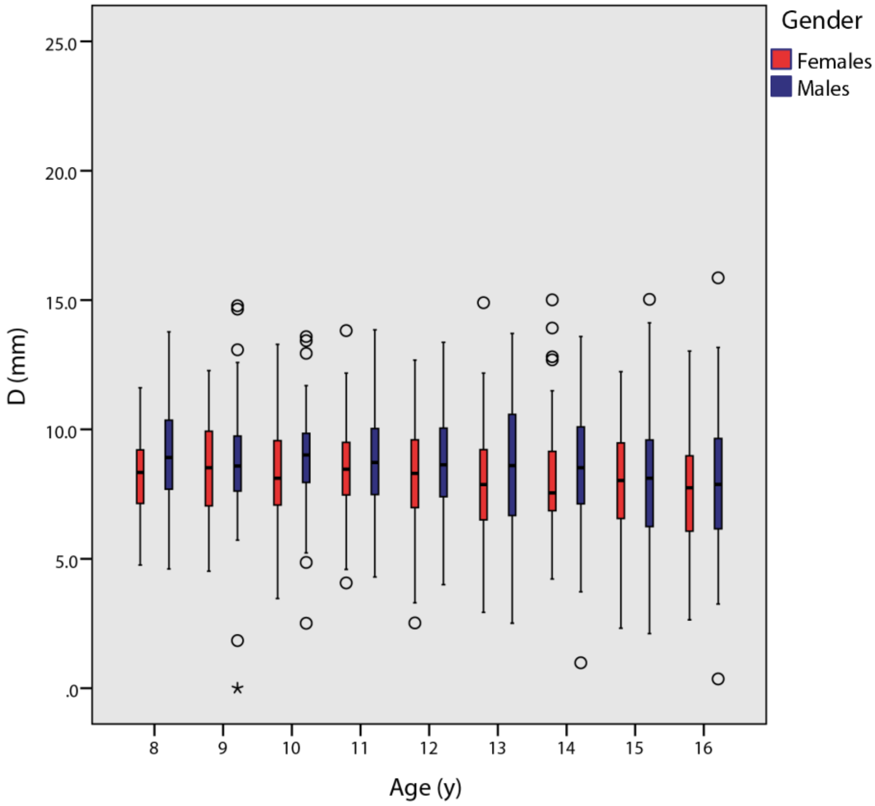

Table 2: Intraclass correlation coefficient (ICC) for intraobserver and interobserver repeatability

	Mean	1 SD	Min.	Max.
Intraobserver	0.948	± 0.142	0.729	0.995
Interobserver	0.933	± 0.141	0.700	0.996

Table 3: Descriptive Analysis: Sample size and distribution

Females	8 years	9 years	10 years	11 years	12 years	13 years	14 years	15 years	16 years
Sample size	55	65	46	70	61	80	100	86	42
Age Mean	8.0	9.0	10.0	11.0	12.0	13.0	14.0	15.0	16.0
Age Min;Max	(8.0 ; 8.0)	(9.0 ; 9.0)	(10.0 ; 10.0)	(11.0 ; 11.0)	(12.0 ; 12.0)	(13.0 ; 13.0)	(14.0 ; 14.0)	(15.0 ; 15.0)	(16.0 ; 16.1)

Males	8 years	9 years	10 years	11 years	12 years	13 years	14 years	15 years	16 years
Sample size	57	59	46	80	66	66	103	110	71
Age Mean	8.0	9.0	10.0	11.0	12.0	13.0	14.0	15.0	16.0
Age Min;Max	(8.0 ; 8.0)	(9.0 ; 9.0)	(10.0 ; 10.0)	(11.0 ; 11.0)	(12.0 ; 12.0)	(13.0 ; 13.0)	(14.0 ; 14.0)	(15.0 ; 15.0)	(16.0 ; 16.0)

Table 4: Descriptive Analysis of the symphyseal variables

		α (°)		H1 (mm)		H2 (mm)		W (mm)		D (mm)	
Age		Mean	95% CI	Mean	95% CI	Mean	95% CI	Mean	95% CI	Mean	95% CI
8	Females	**94.0**	(92.3 ; 95.7)	**20.1**	(19.5 ; 20.7)	**37.0**	(36.4 ; 37.6)	**14.1**	(13.7 ; 14.5)	**8.4**	(8.0 ; 8.8)
	Males	**93.3**	(91.8 ; 94.9)	**19.9**	(19.2 ; 20.5)	**38.0**	(37.2 ; 38.7)	**14.5**	(14.0 ; 14.9)	**9.1**	(8.6 ; 9.7)
9	Females	**95.3**	(93.9 ; 96.7)	**20.2**	(19.6 ; 20.7)	**37.7**	(37.0 ; 38.3)	**14.3**	(13.9 ; 14.6)	**8.4**	(7.9 ; 8.6)
	Males	**95.5**	(94.0 ; 96.9)	**20.3**	(19.6 ; 21.0)	**38.9**	(38.2 ; 39.6)	**14.7**	(14.3 ; 15.1)	**8.8**	(8.2 ; 9.4)
10	Females	**95.5**	(93.5 ; 97.4)	**20.4**	(19.7 ; 21.1)	**38.3**	(37.5 ; 39.1)	**14.6**	(14.1 ; 15.0)	**8.2**	(7.6 ; 8.8)
	Males	**95.8**	(93.5 ; 98.1)	**20.8**	(19.9 ; 21.7)	**39.5**	(38.7 ; 40.2)	**14.8**	(14.4 ; 15.2)	**8.7**	(8.3 ; 9.5)
11	Females	**95.7**	(94.4 ; 97.1)	**20.8**	(20.2 ; 21.4)	**37.9**	(37.3 ; 38.5)	**14.6**	(14.1 ; 15.0)	**8.5**	(8.0 ; 8.9)
	Males	**95.9**	(94.4 ; 97.5)	**20.7**	(20.2 ; 21.3)	**39.7**	(39.1 ; 40.3)	**15.1**	(14.7 ; 15.4)	**8.8**	(8.3 ; 9.2)
12	Females	**95.2**	(93.7 ; 96.8)	**21.0**	(20.4 ; 21.5)	**39.0**	(38.4 ; 39.7)	**14.6**	(14.0 ; 15.2)	**8.2**	(7.7 ; 8.7)
	Males	**97.1**	(95.7 ; 98.6)	**21.1**	(20.5 ; 21.6)	**40.3**	(39.6 ; 40.9)	**15.3**	(14.8 ; 15.7)	**8.7**	(8.2 ; 9.2)
13	Females	**96.0**	(94.7 ; 97.3)	**21.3**	(20.8 ; 21.8)	**39.5**	(38.8 ; 40.2)	**14.8**	(14.4 ; 15.2)	**7.9**	(7.5 ; 8.4)
	Males	**97.8**	(96.2 ; 99.4)	**21.4**	(20.8 ; 22.0)	**41.2**	(40.5 ; 42.0)	**15.4**	(14.9 ; 15.8)	**8.5**	(8.0 ; 9.1)
14	Females	**97.1**	(95.9 ; 98.3)	**22.2**	(21.7 ; 22.6)	**40.4**	(39.8 ; 41.0)	**15.3**	(14.9 ; 15.6)	**8.0**	(7.6 ; 8.4)
	Males	**96.7**	(95.5 ; 97.9)	**22.1**	(21.6 ; 22.6)	**41.9**	(41.2 ; 42.5)	**15.7**	(15.3 ; 16.1)	**8.5**	(8.1 ; 9.0)
15	Females	**96.7**	(95.2 ; 98.2)	**22.3**	(21.8 ; 22.9)	**40.5**	(40.0 ; 40.9)	**15.3**	(14.9 ; 15.7)	**7.9**	(7.5 ; 8.4)
	Males	**97.8**	(96.4 ; 99.1)	**23.4**	(23.0 ; 23.9)	**43.1**	(42.6 ; 43.7)	**16.0**	(15.6 ; 16.3)	**8.1**	(7.7 ; 8.5)
16	Females	**96.1**	(94.1 ; 98.2)	**22.4**	(21.5 ; 23.2)	**40.9**	(40.3 ; 41.5)	**14.9**	(14.2 ; 15.6)	**7.8**	(7.1 ; 8.5)
	Males	**97.1**	(95.6 ; 98.6)	**23.9**	(23.1 ; 24.6)	**44.6**	(43.9 ; 45.3)	**16.5**	(16.1 ; 16.9)	**7.9**	(7.3 ; 8.5)

Table 5: Symphyseal configuration: Correlations of Absolute measurements to age

(Correlation coefficient and p-value)

	α (°)		H1 (mm)		H2 (mm)		W (mm)		D (mm)	
	Females	**Males**	**Females**	**Males**	**Females**	**Males**	**Females**	**Males**	**Females**	**Males**
Age	0.105	0.137	0.326	0.411	0.421	0.544	0.198	0.316	-0.100	-0.149
	0.010 *	0.000 **	0.000 **	0.000 **	0.000 **	0.000 **	0.000 **	0.000 **	0.014 *	0.000 **

* significance level at $p < 0.05$

** significance level at $p < 0.01$

Table 6: Symphyseal configuration: Correlations of Absolute measurements to α

(Correlation coefficient and p-value)

	H1				H2				W				D			
Age	**Females**		**Males**		**Females**		**Males**		**Females**		**Males**		**Females**		**Males**	
8	0.102		-.008		0.137		0.029		0.03		-0.033		**0.309**		0.155	
	0.461	*n.s.*	*0.951*	*n.s.*	*0.32*	*n.s.*	*0.833*	*n.s.*	*0.826*	*n.s.*	*0.809*	*n.s*	***0.022***	*	*0.249*	*n.s.*
9	0.021		-.099		0.129		0.096		-0.012		0.096		**0.356**		**0.288**	
	0.87	*n.s.*	*0.455*	*n.s.*	*0.308*	*n.s.*	*0.469*	*n.s.*	*0.925*	*n.s.*	*0.468*	*n.s.*	***0.004***	**	***0.027***	*
10	-0.003		-0.214		0.095		-0.099		**0.432**		-0.09		**0.546**		**0.386**	
	0.982	*n.s.*	*0.153*	*n.s.*	*0.53*	*n.s.*	*0.511*	*n.s.*	***0.003***	**	*0.55*	*n.s.*	***0.000***	**	***0.008***	**
11	0.016		0.151		0.032		0.142		0.145		0.075		**0.325**		**0.501**	
	0.894	*n.s.*	*0.181*	*n.s.*	*0.795*	*n.s.*	*0.208*	*n.s.*	*0.232*	*n.s*	*0.51*	*n.s.*	***0.006***	**	***0.000***	**
12	*-0.168*		-0.129		0.07		-0.045		0.042		-0.004		0.158		**0.355**	
	0.197	*n.s.*	*0.304*	*n.s.*	*0.594*	*n.s.*	*0.772*	*n.s.*	*0.748*	*n.s.*	*0.972*	*n.s.*	*0.223*	*n.s.*	***0.003***	**
13	*-0.038*		-0.070		**0.238**		-0.006		-0.017		0.181		**0.416**		**0.418**	
	0.74	*n.s.*	*0.576*	*n.s.*	***0.034***	*	*0.964*	*n.s.*	*0.88*	*n.s.*	*0.145*	*n.s.*	***0.000***	**	***0.000***	**
14	*0.067*		0.047		0.143		0.096		-0.029		**0.223**		**0.432**		**0.530**	
	0.506	*n.s.*	*0.635*	*n.s.*	*0.156*	*n.s.*	*0.335*	*n.s.*	*0.778*	*n.s.*	***0.024***	*	***0.005***	**	***0.000***	**
15	*0.057*		-0.018		-0.036		0.006		0.211		0.042		**0.502**		**0.526**	
	0.6	*n.s.*	*0.855*	*n.s.*	*0.745*	*n.s.*	*0.954*	*n.s.*	*0.051*	*n.s.*	*0.663*	*n.s.*	***0.001***	**	***0.000***	**
16	*0.041*		-0.067		0.193		-0.215		0.274		0.017		**0.363**		**0.528**	
	0.797	*n.s.*	*0.581*	*n.s.*	*0.221*	*n.s.*	*0.072*	*n.s.*	*0.079*	*n.s.*	*0.891*	*n.s.*	*0.105*	*n.s.*	***0.003***	**

* significance level at $p < 0.05$

** significance level at $p < 0.01$

Table 7: Symphyseal configuration: Correlations of Ratios to α

(Correlation coefficient and p-value)

	H1/W				H2/W				D/W			
Age	**Females**		**Males**		**Females**		**Males**		**Females**		**Males**	
8	0.092		0.029		0.047		0.039		**-0.314**		-0.238	
	0.504	*n.s.*	*0.828*	*n.s.*	*0.735*	*n.s.*	*0.771*	*n.s.*	***0.020***	*	*0.075*	*n.s.*
9	0.033		-0.11		0.093		-0.015		**-0451**		**-0.296**	
	0.796	*n.s.*	*0.407*	*n.s.*	*0.460*	*n.s.*	*0.912*	*n.s.*	***0.000***	**	***0.023***	*
10	**-0.359**		-0.136		**-0.324**		0.008		**-0.434**		**-0.468**	
	0.014	*	*0.369*	*n.s.*	***0.028***	*	*0.956*	*n.s.*	***0.003***	**	***0.001***	**
11	-0.133		-0.196		-0.147		0.015		**-0.279**		**-0.545**	
	0.273	*n.s.*	*0.082*	*n.s.*	*0.225*	*n.s.*	*0.892*	*n.s.*	***0.019***	*	***0.000***	**
12	0.011		-0.124		0.048		-0.036		-0.009		**-0.407**	
	0.93	*n.s.*	*0.322*	*n.s.*	*0.713*	*n.s.*	*0.775*	*n.s.*	*0.942*	*n.s.*	***0.001***	**
13	0.06		-0.242		0.183		-0.198		**-0.513**		**-0.445**	
	0.958	*n.s.*	*0.051*	*n.s.*	*0.104*	*n.s.*	*0.111*	*n.s.*	***0.000***	**	***0.000***	**
14	0.071		-0.161		0.108		-0.166		**-0.374**		**-0.537**	
	0.481	*n.s.*	*0.105*	*n.s.*	*0.284*	*n.s.*	*0.095*	*n.s.*	***0.000***	**	***0.000***	**
15	-0.147		-0.046		-0.2		-0.042		**-0.427**		**-0.590**	
	0.176	*n.s.*	*0.630*	*n.s.*	*0.064*	*n.s.*	*0.664*	*n.s.*	***0.000***	**	***0.000***	**
16	-0.242		-0.075		-0.197		-0.136		**-0.436**		**-0.574**	
	0.122	*n.s.*	*0.534*	*n.s.*	*0.211*	*n.s.*	*0.258*	*n.s.*	***0.004***	**	***0.000***	**

* significance level at $p < 0.05$

** significance level at $p < 0.01$

Table 8: Skeletal pattern: Correlations of angulations to α

(Correlation coefficient and p-value)

	SpaSpp/MGo				MGo/Ar			
Age	**Females**		**Males**		**Females**		**Males**	
8	-0.158		**-0.299**		-0.261		**0.314**	
	0.251	*n.s.*	***0.024***	*	*0.054*	*n.s.*	***0.017***	*
9	-0.091		-0.254		-0.198		-0.201	
	0.469	*n.s.*	*0.053*	*n.s.*	*0.114*	*n.s.*	*0.126*	*n.s.*
10	**-0.442**		**-0.463**		**-0.409**		**-0.33**	
	0.002	**	***0.001***	**	***0.005***	**	***0.25***	*
11	-0.221		**-0.302**		-0.214		**-0.404**	
	0.066	*n.s.*	***0.007***	**	*0.076*	*n.s.*	***0.000***	**
12	-0.159		**-0.295**		-0.115		**-0.409**	
	0.222	*n.s.*	***0.016***	*	*0.379*	*n.s.*	***0.044***	**
13	**-0.268**		**-0.333**		**-0.326**		-0.168	
	0.016	*	***0.006***	**	***0.003***	**	*0.177*	*n.s.*
14	**-0.391**		**-0.394**		**-0.439**		**-0.401**	
	0.000	**	***0.000***	**	***0.000***	**	***0.000***	**
15	**-0.48**		**-0.397**		**-0.545**		**-0.548**	
	0.000	**	***0.000***	**	***0.000***	**	***0.000***	**
16	**-0.331**		**-0.355**		**-0.383**		**-0.322**	
	0.032	*	***0.002***	**	*0.012*	*	***0.006***	**

* significance level at $p < 0.05$

** significance level at $p < 0.01$

5. Discussion

The rationale behind this present study was to investigate influencing factors for lower incisor angulation. This angulation has a twofold relevance. First, the lower incisors play an essential role in orthodontic treatment planning because of their very restricted anatomical leeway within the symphysis. It has been demonstrated that excessive sagittal movements or tipping may result in significant recessions of the gingival margin and in bony dehiscences (Batenhorst *et al.*, 1974; Dorfman, 1978; Hollender *et al.*, 1980; Steiner *et al.*, 1981; Wennstrom *et al.*, 1987; Sarikaya *et al.*, 2002; Yared *et al.*, 2006), and although these recessions and dehiscences could not be observed in all investigations (Artun and Krogstad, 1987; Ruf *et al.*, 1998; Djeu *et al.*, 2002; Melsen and Allais, 2005), reference values for incisor angulation and symphyseal dimensions of both genders at all ages will prove to be useful.

Second, as mentioned in the introduction, the use of lateral cephalograms in orthodontic diagnosis and treatment planning is undisputed. One of the clinical goals of pretreatment lateral cephalograms is to assess the individual's skeletal characteristics in order to predict future growth tendencies. Many attempts have therefore been made to discern whether symphyseal morphology may contain information about the growth pattern of the mandible (Ricketts, 1960; Bjork, 1969; Sassouni, 1969; Skieller *et al.*, 1984; Lee *et al.*, 1987; Aki *et al.*, 1994; Leslie *et al.*, 1998; Papamanou *et al.*, 2012). It is therefore of interest to evaluate whether the angulation of the lower incisors could be linked to a certain symphyseal morphology or skeletal pattern. Any association would have clinical relevance in treatment planning, as it implies that these possible co-factors would have to be respected when deciding which angulation the lower incisors should have.

5.1 The Zurich craniofacial Growth study

Several notable craniofacial studies were published from the seventies to the nineties of the last century that are now used routinely as references (Riolo *et al.*, 1974; Prahl-Andersen *et al.*, 1979; Bishara, 1981; Roche, 1992; Bhatia and Leighton, 1993; Hunter *et al.*, 1993; el-Batouti *et al.*, 1994). Hence, the question arises as to why would it be necessary to use the data of another, yet unpublished growth study? The reasons are several. Primarily, the uncontested genetic influence on craniofacial growth makes it necessary to establish reference values for every population. No reference data exists that can be applied to *all* white subjects. It has been shown that sagittal and vertical jaw relationships have diverse growth pattern, even within different samples of white untreated subjects (Trenouth *et al.*, 1999; van Diepenbeek *et al.*, 2009). Absolute sizes might differ and children from different regions might expect to mature at different rates and ages (van Diepenbeek *et al.*, 2009).

Apart from this, the use of the Zurich craniofacial Growth study is legitimate because of its uniqueness in two ways. First, it enables to derive a large sample size of untreated subjects of the same cohort without pooling. This stands in contrast to previous studies which used sometimes far smaller sample sizes or occasionally even the data of treated subjects (Lee *et al.*, 1987). The abundance of material is not just a nice feature. It permits division of the data in subgroups by gender and age, while leaving every subgroup with enough statistical power.

Second, the Zurich craniofacial Growth study is matchless because it is the sole growth study in which the data collection was performed always very close to the subject's birthday. The implication of this fact is that no thresholding is necessary when dividing the sample in different age groups.

5.2 Reference values for incisor angulation and symphyseal dimensions

Sexual dimorphism in the facial dimensions is a fact that has been established by various analyses (Schudy, 1965; Bishara and Jakobsen, 1985; Siriwat and Jarabak, 1985; Nanda, 1988). Therefore, the present data had to be divided by gender in order to maintain the homogeneity of the sample. This is a crucial remark, since other comparative studies (Skieller *et al.*, 1984; Lee *et al.*, 1987; Leslie *et al.*, 1998) combined females and males for statistical analysis. This fact might attest for some dissimilar results and conclusions.

The results of this present study demonstrate an age-dependency of lower incisor angulation. Throughout childhood, the lower incisors become significantly more proclined. This phenomenon is more accentuated in males with an increase of nearly four degrees in average than in females with an increase of a little more than two degrees in average. In general, males had more proclined lower incisors than females. In regard to the angulation increase, most of the changes occurred during the first four years of observation (from 8 till 12 years of age). These findings are in accordance with the reference values established by Bhatia and Leighton (Table 10), who confirmed an increase of lower incisor angulation between 8 and 12 years of age for both sexes as well as a generally more proclined position in males (Bhatia and Leighton, 1993). However, the reference values of Riolo (Table 9) only corroborate the observation of a more pronounced proclination for males, but they do not reflect an age-dependent increase (Riolo *et al.*, 1974).

This present study examined symphyseal parameters in order to establish reference values and to associate those values to lower incisor angulation. Reference values of symphyseal dimensions are essential, as it is commonly agreed that an especially narrow symphysis is an etiological factor in the development of fenestrations and dehiscences (Artun and Krogstad, 1987; Wehrbein *et al.*, 1996). Moreover, as stated in the introduction, the size and the inclination of the symphysis are frequently been valued as growth predictors of subsequent mandibular development (Bjork, 1969; Skieller *et al.*, 1984; Aki *et al.*, 1994; Leslie *et al.*, 1998).

Although symphyseal parameters have been studied in earlier works already, the present results can only be compared to those numbers with caution. On the one hand, the definition and identification of symphyseal landmarks may differ from author to author, rendering a direct comparison of absolute values questionable. On the other hand, the individual variation of all the parameters measured is substantial enough to require that caution should be used when mean values are applied to individual cases (Baumrind *et al.*, 1992) or compared to each other. Yet, some tendencies can unmistakably be discerned when juxtaposing the data. In agreement with our findings, other authors also attest a continuous increase of symphyseal height throughout the entire observed childhood (Riolo *et al.*, 1974; Bhatia and Leighton, 1993; Aki *et al.*, 1994), which stands in contrast to the unaltered lower incisor angulation in later childhood. Furthermore, two additional observations are supported by literature: First, a distinct gender dissimilarity with an unanimously observed twofold increase for males. Second, the very modest gain in symphyseal height up to point B (distance H1) (Bhatia and Leighton, 1993) and the excessive vertical increase for symphyseal height up to the tip of the lower incisors (distance H2) (Riolo *et al.*, 1974; Aki *et al.*, 1994). This discovery, i.e. the fact that most of the changes occur in the dentoalveolar part of the symphysis, seems to reflect previous statements that the anterior basal part of the symphysis remains a stable landmark (Bjork, 1963; 1969).

Similarly, only little variation can be witnessed in symphyseal width (distance W) with an increase of one millimeter for females and two millimeters for males over the entire observed period. This is in complete agreement with Riolo et al. (Riolo *et al.*, 1974), but not with Aki et al. who measured a more significant increase in the sagittal dimension of the symphysis (Aki *et al.*, 1994).

Aki (Aki *et al.*, 1994) remarked that the growth changes of the symphysis occur mainly during puberty. This observation is not in agreement with our findings which could not attest a pubertal growth peak for any symphyseal dimension.

5.3 Correlation of lower incisor angulation to different variables

Based on the statistical results, it is safe to presume that lower incisor inclination is not associated to symphyseal height. The width of the symphysis also does not correlate to the angulation of lower incisor. Similarly, the assessed height to width ratios (H1/W and H2/W) revealed no relationship. This is an interesting finding, since symphyseal morphology and expressly symphyseal ratios have been linked to mandibular growth patterns (Ricketts, 1960; Aki *et al.*, 1994): Aki described an association between a horizontal mandibular growth pattern and a symphysis with small height, large depth and small height to depth ratio. Conversely, a vertical growth pattern was linked to a large height, small depth and large height to depth ratio. A further study attested that the symphyseal development might be linked to vertical facial dimensions: an excessive dental overbite coincided with a wider shape of the sypmphysis (Beckmann *et al.*, 1998b) and long-faced subjects were associated with a large mandibular alveolar height (Beckmann *et al.*, 1998a). Our results seem to indicate that although an association might exist between symphyseal morphology and the overall mandibular growth pattern, this correlation cannot be confirmed for the same symphyseal variables and the inclination of lower incisors.

Yet, maybe unexpectedly, according to our results symphyseal depth noticeably correlates with the angulation of lower incisors. This is a striking, as yet un-described revelation. The natural inclination of the lower incisor seems to be linked to the available space posteriorly. This fact is probably not appreciated enough. In regard to symphyseal configuration, the focus has been laid mostly on the anterior part of the symphysis in order to disclose a certain skeletal pattern and, with it, the proclination of lower incisors. Our study, however, indicates that the posterior dimension, and not the morphology of the anterior part of the symphysis, seems to be of higher relevance to determine the correct inclination. Further studies should investigate in the interpretation of this correlation.

In retrospect, perhaps a better way to establish this association would have been to investigate the correlation of lower incisor angulation to the posterior space available, as defined by the *apex of the lower incisors*. This would certainly more aptly describe the connection between the posterior space and the incisor position. The obvious constraint of this approach is, however, that the apex position is very often difficult to locate due to overlapping structures such as the root of the canines. Furthermore, root growth might not been terminated in the observed younger age group rendering the apex an unstable landmark.

In order to determine a link between the skeletal pattern and the angulation of the lower incisors, two representative parameters, indicative for the skeletal background, were selected: The divergence of the jaws and the gonion angle. The divergence of the jaws is commonly used to categorize the rotation pattern (Sassouni, 1969; Aki *et al.*, 1994; Mangla *et al.*, 2011) and, as mentioned in the introduction, the gonion region is, next to symphyseal morphology, the parameter with the best predictive value for growth pattern (Sassouni, 1969; Opdebeeck and Bell, 1978; Trouten *et al.*, 1983; Cangialosi, 1984; Fields *et al.*, 1984; Nanda, 1988).

Both the divergence of the jaws and the gonion angle show significant to highly significant negative correlations to the lower incisor angulation. A pronounced divergence of the jaws and an obtuse gonion angle are related to retroclined incisors. As noted in the results, a certain tendency can be observed: The correlation seems more solid for males than females, and it is incontestably more prominent in later stages of childhood.

This finding contains clinically relevant information. It is evident that if the natural inclination is dependent on the subject's skeletal pattern, it should be assumed that in treatment planning, this association should be respected as well. Moreover, the fact that the link between lower incisor inclination and skeletal background is more significant in late puberty might be the reason why this association is not fostered in all studies published, especially in those studies focusing on younger subjects.

5.4 Limitations

A notable limitation to this study is the fact that only vertical skeletal parameters were evaluated. It would have been of interest to discern whether sagittal skeletal variables would account for changes in the inclination of lower incisors. This hypothesis has yet to be verified and should be within the scope of a further study.

A further constraint is the fact that only subjects 8 to 16 years of age were assessed. An evaluation of subjects above the ages 16, notably the period around the end of growth, would definitely have been appealing. Although the Zurich craniofacial Growth study contains subjects up to the age of 18, the sample size over the ages of 16 is too small to enable a solid statistical analysis.

5.4 Conclusions

This study investigated the inclination of lower incisor angulation with the aim to obtain reference values from an untreated cohort for incisor inclination and symphyseal dimensions. The investigation of affecting factors revealed that the lower incisor inclination is not associated to most symphyseal distances, except symphyseal depth. Lower incisor angulation, however, is linked to the subject's sex, age and skeletal pattern.

The mean values of the incisor angulation were obtained for every age and gender, but the wide inter-individual variety renders the use of the mean values as questionable. Our results imply that not the mean values, but rather the influencing factors such as the symphyseal depth and the skeletal background should be respected when evaluating the natural inclination of lower incisors and establishing a treatment planning.

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7. Appendix

7.1 Tables of reference values

Table 9: Reference values of Riolo, Moyers, McNamara and Hunter
(Mean values of present study are in italic)

Age		H2 (mm) Mean	H2 (mm) SD	*H2 (mm) Mean*	W (mm) Mean	W (mm) SD	*W (mm) Mean*	α (°) Mean	α (°) SD	*α (°) Mean*
8	**Female**	**37.8**	2.2	***37.0***	**15.1**	1.6	***14.1***	**93.1**	7.0	***94.0***
	Males	**39.6**	2.4	***38.0***	**15.9**	1.3	***14.5***	**94.0**	5.7	***93.3***
9	**Female**	**38.9**	2.5	***37.7***	**15.2**	1.8	***14.3***	**93.9**	7.2	***95.3***
	Males	**40.7**	2.4	***38.9***	**16.0**	1.4	***14.7***	**94.7**	5.7	***95.5***
10	**Female**	**40.0**	2.6	***38.3***	**15.6**	1.9	***14.6***	**93.8**	6.8	***95.5***
	Males	**41.9**	2.4	***39.5***	**16.3**	1.3	***14.8***	**95.8**	5.1	***95.8***
11	**Female**	**40.5**	2.6	***37.9***	**15.7**	1.8	***14.6***	**93.3**	6.0	***95.7***
	Males	**42.9**	2.7	***39.7***	**16.4**	1.5	***15.1***	**95.8**	5.4	***95.9***
12	**Female**	**41.1**	2.2	***39.0***	**15.8**	1.8	***14.6***	**94.7**	6.5	***95.2***
	Males	**43.3**	2.7	***40.3***	**16.7**	1.4	***15.3***	**95.1**	5.9	***97.1***
13	**Female**	**42.0**	2.6	***39.5***	**16.2**	2.0	***14.8***	**93.2**	6.0	***96.0***
	Males	**44.2**	3.1	***41.2***	**16.9**	1.6	***15.4***	**96.1**	7.1	***97.8***
14	**Female**	**42.1**	2.6	***40.4***	**16.3**	1.8	***15.3***	**94.3**	6.8	***97.1***
	Males	**45.6**	3.6	***41.9***	**17.6**	1.8	***15.7***	**94.8**	7.2	***96.7***
15	**Female**	**42.0**	3.2	***40.5***	**16.0**	1.7	***15.3***	**92.0**	6.4	***96.7***
	Males	**46.6**	3.4	***43.1***	**17.6**	1.7	***16.0***	**94.8**	7.1	***97.8***
16	**Female**	**41.5**	3.1	***40.9***	**16.0**	1.8	***14.9***	**92.0**	9.0	***96.1***
	Males	**48.9**	3.0	***44.6***	**18.1**	1.6	***16.5***	**95.3**	6.6	***97.1***

Table 10: Reference values of Bathia and Leighton

(Mean values of present study are in italic)

Age		B to Me-Go (mm) Mean	B to Me-Go (mm) SD	*H1 (mm) Mean*	Lower incisor to Me-Go (mm) Mean	Lower incisor to Me-Go (mm) SD	*H2 (mm) Mean*	Lower incisor to Me-Go (°) Mean	Lower incisor to Me-Go (°) SD	*α (°) Mean*
8	**Female**	**17.6**	1.4	***20.1***	**32.8**	2.3	***37.0***	**89.7**	**6.7**	***94.0***
	Males	**17.9**	1.6	***19.9***	**33.3**	2.2	***38.0***	**89.0**	**6.6**	***93.3***
9	**Female**	**17.9**	1.6	***20.2***	**33.5**	2.4	***37.7***	**90.4**	**7.0**	***95.3***
	Males	**18.1**	1.5	***20.3***	**34.2**	2.4	***38.9***	**89.7**	**6.4**	***95.5***
10	**Female**	**18.2**	1.6	***20.4***	**34.1**	2.5	***38.3***	**90.8**	**6.5**	***95.5***
	Males	**18.3**	1.5	***20.8***	**35.0**	2.5	***39.5***	**90.2**	**6.6**	***95.8***
11	**Female**	**18.7**	1.6	***20.8***	**34.7**	2.5	***37.9***	**91.0**	**7.0**	***95.7***
	Males	**18.6**	1.5	***20.7***	**35.6**	2.7	***39.7***	**91.1**	**6.9**	***95.9***
12	**Female**	**19.2**	1.6	***21.0***	**35.3**	2.6	***39.0***	**90.7**	**6.6**	***95.2***
	Males	**19.1**	1.5	***21.1***	**36.2**	2.8	***40.3***	**91.7**	**7.3**	***97.1***
13	**Female**	**19.5**	1.7	***21.3***	**35.8**	2.7	***39.5***	**90.1**	**6.7**	***96.0***
	Males	**19.6**	1.6	***21.4***	**36.9**	2.9	***41.2***	**91.8**	**7.4**	***97.8***
14	**Female**	**19.9**	1.7	***22.2***	**36.2**	2.7	***40.4***	**89.7**	**6.8**	***97.1***
	Males	**20.2**	1.7	***22.1***	**37.9**	3.1	***41.9***	**91.8**	**7.4**	***96.7***
15	**Female**	**20.1**	1.8	***22.3***	**36.4**	2.7	***40.5***	**89.6**	**6.9**	***96.7***
	Males	**20.8**	1.9	***23.4***	**38.7**	3.2	***43.1***	**91.8**	**7.5**	***97.8***
16	**Female**	**20.3**	1.8	***22.4***	**36.6**	2.7	***40.9***	**89.4**	**6.9**	***96.1***
	Males	**21.3**	2.0	***23.9***	**39.3**	3.2	***44.6***	**91.7**	**7.7**	***97.1***

7.2 Legal approval of the Federal Commission of Experts for Professional Secrecy in Medical Research

Sonderbewilligung
zur Offenbarung des Berufsgeheimnisses zu Forschungszwecken
im Bereich der Medizin und des Gesundheitswesens

Die Expertenkommission für das Berufsgeheimnis in der medizinischen Forschung,
hat im Zirkularverfahren vom 25. Juli 2011,
gestützt auf Artikel 321^{bis} des Strafgesetzbuches (StGB; SR *311.0*);
Artikel 1, 2, 9, 10, 11 und 13 der Verordnung vom 14. Juni 1993 über
die Offenbarung des Berufsgeheimnisses im Bereich der medizinischen Forschung
(VOBG; SR *235.154*);
in Sachen *Zentrum für Zahnmedizin, Universität Zürich, Projekt «Zürcher kraniale Wachstumsstudie – eine retrospektive Analyse von Röntgenbildern unbehandelter Kinder»*, betreffend Gesuch vom 16. Juni 2011 für eine Sonderbewilligung zur Offenbarung des Berufsgeheimnisses im Sinne von Artikel 321^{bis} StGB zu Forschungszwecken im Bereich der Medizin und des Gesundheitswesens,
verfügt:

1. Bewilligungsnehmer

a) Dr. med. dent. Raphael Patcas, Oberassistent an der Klinik für Kieferorthopädie und Kinderzahnmedizin des Zentrums für Zahnmedizin der Universität Zürich, wird als verantwortlichem Projektleiter unter nachfolgenden Bedingungen und Auflagen eine Sonderbewilligung gemäss Artikel 321^{bis} StGB sowie Artikel 2 VOBG zur Entgegennahme nicht anonymisierter Daten im Rahmen von Ziffer 2 und 3 erteilt.

b) Dr. med. dent. Luca Signorelli, externer Mitarbeiter der Klinik für Kieferorthopädie und Kinderzahnmedizin des Zentrums für Zahnmedizin der Universität Zürich, und Dr. med. dent. Michael Hänggi, Oberassistent an der Klinik für Kieferorthopädie und Kinderzahnmedizin des Zentrums für Zahnmedizin der Universität Zürich, wird unter nachfolgenden Bedingungen und Auflagen eine Sonderbewilligung gemäss Artikel 321^{bis} StGB sowie Artikel 2 VOBG zur Entgegennahme nicht anonymisierter Daten im Rahmen von Ziffer 2 und 3 erteilt.

Die Bewilligungsnehmer haben eine Erklärung über die ihnen gemäss Artikel 321^{bis} StGB auferlegte Schweigepflicht zu unterzeichnen und der Expertenkommission zuzustellen.

2. Umfang der Sonderbewilligung

a) Der Ärzteschaft der Klinik für Kieferorthopädie und Kinderzahnmedizin des Zentrums für Zahnmedizin der Universität Zürich sowie deren Hilfspersonen wird die Bewilligung erteilt, den Bewilligungsnehmern gemäss Ziffer 1 Zugang zu den Daten und Röntgenbildern (Handröntgen und seitliches Fernröntgenbild) zu gewähren, die in der Zeit von 1981–1984 im Rahmen eines damals durchgeführten Projektes von insgesamt 884 Zürcher Schulkindern erhoben bzw. angefertigt wurden. Die Datenbekanntgaben dürfen einzig dem in Ziffer 3 umschriebenen Zweck dienen.

b) Mit der Bewilligungserteilung entsteht für niemanden die Pflicht zur Datenbekanntgabe.

3. Zweck der Datenbekanntgabe

Die gestützt auf die vorliegende Bewilligung bekannt gegebenen Personendaten, die dem medizinischen Berufsgeheimnis gemäss Artikel 321 StGB unterstehen, dürfen nur für das Projekt «Zürcher kraniale Wachstumssstudie – eine retrospektive Analyse von Röntgenbildern unbehandelter Kinder» verwendet werden.

4. Schutz der bekannt gegebenen Daten

Die Bewilligungsnehmer haben die nach den datenschutzrechtlichen Bestimmungen erforderlichen technischen und organisatorischen Massnahmen zu treffen, um die Daten vor unbefugtem Zugriff zu schützen.

5. Verantwortlichkeit für den Schutz der bekannt gegebenen Daten

Die Verantwortung für den Schutz der bekannt gegebenen Daten trägt der verantwortliche Projektleiter, Dr. med. dent. Raphael Patcas.

6. Auflagen

a) Die für das Projekt benötigten Daten sind so bald als möglich zu anonymisieren.

b) Unberechtigten Personen darf kein Einblick in nicht anonymisierte Daten gewährt werden.

c) Die Massnahmen gemäss Ziffer 4 haben dem Stand der Technik zu entsprechen.

d) Nicht anonymisierte Daten sind zu vernichten, sobald sie nicht mehr benötigt werden.

e) Projektergebnisse dürfen nur in vollständig anonymisierter Form veröffentlicht werden, d.h. es dürfen keinerlei Rückschlüsse auf die betroffenen Personen möglich sein. Nach Abschluss des Projektes ist der Expertenkommission ein Exemplar allfälliger Publikationen zur Kenntnisnahme zuzustellen.

f) Die Bewilligungsnehmer haben die zuständige Ärzteschaft der Klinik für Kieferorthopädie und Kinderzahnmedizin des Zentrums für Zahnmedizin der Universität Zürich über den Umfang der erteilten Bewilligung schriftlich zu informieren. Das Schreiben ist vor dem Versand dem Sekretariat der Expertenkommission zu Handen des Präsidenten zur Kenntnisnahme zuzustellen.

7. Rechtsmittelbelehrung

Gegen diese Verfügung kann gemäss Artikel 44 ff. des Bundesgesetzes vom 20. Dezember 1968 über das Verwaltungsverfahren (VwVG; SR *172.021*) innert 30 Tagen seit deren Eröffnung bzw. Publikation beim Bundesverwaltungsgericht, Postfach, 3000 Bern 14, Beschwerde erhoben werden. Die Beschwerde ist im Doppel einzureichen und hat die Begehren, deren Begründung mit Angabe der Beweismittel und die Unterschrift der beschwerdeführenden Partei oder ihres Vertreters oder ihrer Vertreterin zu enthalten. Die angefochtene Verfügung und die als Beweismittel angerufenen Urkunden sind beizulegen.

8. Mitteilung und Publikation

Diese Verfügung wird den Bewilligungsnehmern und dem Eidgenössischen Datenschutz- und Öffentlichkeitsbeauftragten schriftlich mitgeteilt. Das Verfügungsdispositiv wird im Bundesblatt veröffentlicht. Wer zur Beschwerde legitimiert ist, kann innert der Beschwerdefrist beim Sekretariat der Expertenkommission, Bundesamt für Gesundheit, Abteilung Recht, 3003 Bern, nach telefonischer Voranmeldung (031 322 94 94) Einsicht in die vollständige Verfügung nehmen.

18. Oktober 2011

Expertenkommission für das Berufsgeheimnis
in der medizinischen Forschung

Der Vizepräsident: Rudolf Bruppacher